

Message Text

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PAGE 01 STATE 178170
ORIGIN HEW-06

INFO OCT-01 EA-12 ISO-00 OES-09 /028 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: UJWALSH, III
DHEW/PHS/OASH/OIH: REVANS
EA/J EFEATHERSTONE(INFO)

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P 142058Z JUL 78
FM SECSTATE WASHDC
TO AMEMBASSY TOKYO PRIORITY

UNCLAS STATE 178170

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, JA

SUBJECT: FDA REPRESENTATIVE PROVIDING TECHNICAL AND
CONSULTATIVE ASSISTANCE TO JAPANESE PHARMACEUTICAL FIRMS

1. FDA ADVISES THAT MR. HAROLD SANDERS, CONSUMER SAFETY OFFICER, CINCINNATI DISTRICT OFFICE AND MR. LOUIE F. TURDER, DEPUTY CHIEF, OFFICE OF EXECUTIVE DIRECTOR FOR REGIONAL OPERATIONS WILL BE IN JAPAN JULY 15-AUGUST 14, 1978.
2. THE FDA REPRESENTATIVE:S WILL VISIT 9 PHARMACEUTICAL FIRMS TO DETERMINE IF THE FIRM'S FACILITIES AND OPERATIONS ARE IN ACCORDANCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS AND WILL REPORT ANY SIGNIFICANT DEVIATIONS WHICH WOULD HAVE AN ADVERSE EFFECT UPON THE SAFETY AND/OR EFFICACY OF DRUGS BEING IMPORTED INTO THE UNITED STATES.

3. ITINERARY AS FOLLOWS:
JULY 15 - ARRIVE OSAKA, JAPAN
JULY 16 - TRAVEL OSAKA TO TAKUYANNA
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JULY 17-18 - VISIT TAKEDA/HIKARI
JULY 19 - TRAVEL OSAKA TO TOYAMA
JULY 20-21 - VISIT NIPPON-SODA
JULY 22 - TRAVEL TOYAMA TO TOKYO

JULY 24-25 - VISIT DELMONT LABS SHINJUKU/NERIMA
JULY 26 - TRAVEL TOKYO TO FUKOURU

JULY 27-28 - VISIT DELMONT LABS KYUSHU UNIVERSITY

JULY 31 - VISIT AJINOMOTO/KYUSHU

AUGUST 1 - TRAVEL TOKYO TO KAWASKI

AUGUST 2 - VISIT AJINOMOTO/KANASKI

AUGUST 3 - TRAVEL KAWAKSI TO TOKYO

AUGUST 4 - VISIT EIR AJINOMOTO

AUGUST 7-9 - VISIT HIKARI CHEMICALS

AUGUST 10-12 - VISIT SANKYO

AUGUST 14 - DEPART TOKYO, JAPAN FOR HONOLULU, HAWAII

4. ASSISTANCE OF EMBASSY WILL NOT BE REQUIRED. CHRISTOPHER

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Message Attributes

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